510(k) Summary

JUL 24 2009

Sponsor: SIGNUS Medizintechnik GmbH
Carl-Zeiss-Strasse 2
D-63755 Alzenau, GERMANY
Tel. + 49 (0) 6023 9166-136
Fax + 49 (0) 6023 9166-161
Url: http://www.signus-med.de

Contact Person: Jörg Degen, Regulatory Affairs, QM

Proposed Trade Name: NUBIC™ device

Device Classification Class II

Classification Name: Spinal vertebral body replacement device; Intervertebral fusion device with bone graft, cervical

Regulation: 888.3060; 888.3080

Device Product Code: MQP; ODP

Device Description: The basic shape of the NUBIC device is a rectangular frame. The upper and lower aspects of the implant are open with surface spikes which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies. The device is available in a variety of sizes enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition. A connecting screw is available which permits attachment of the NUBIC (without strut) to the Signus TOSCA II anterior cervical plate if the surgeon so chooses.

Intended Use: When used as a vertebral body replacement, the NUBIC devices are indicated for use in skeletally mature patients to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The NUBIC device may be implanted singularly or in pairs and may be used with allograft or autograft.

When used as an intervertebral fusion device, the NUBIC devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One NUBIC device is used per intervertebral space. A connecting screw is available which allows the NUBIC device (without strut) to be physically attached to the SIGNUS TOSCA or TOSCA II anterior cervical plate systems if desired.

Materials: The NUBIC device is manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) as described by ASTM F2026. Integral marker pins in the implants and the connecting screw are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Substantial Equivalence: Documentation was provided which demonstrated the NUBIC to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and performance.

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Url: http://www.signus-med.de

Contact Person: Jörg Degen, Regulatory Affairs, QM

Proposed Trade Name: RABEA™ device

Device Classification Class II

Classification Name: Spinal vertebral body replacement device; Intervertebral fusion device with bone graft, cervical

Regulation: 888.3060; 888.3080

Device Product Code: MQP; ODP

Device Description: The basic shape of the RABEA device is a rectangular frame. The upper and lower aspects of the implant are open with surface spikes which assist in the positive anchorage and seating of the implant between the superior and inferior vertebral bodies. The device is available in a variety of sizes enabling the surgeon to choose the size best suited to the individual pathology and anatomical condition.

Intended Use: When used as a vertebral body replacement, the RABEA devices are indicated for use in skeletally mature patients to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The RABEA device is intended to be implanted in pairs and may be used with allograft or autograft.

When used as an intervertebral fusion device, the RABEA devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One RABEA device is used per intervertebral space.

Materials: The RABEA device is manufactured from either titanium alloy (Ti-6Al-4V) as described by ASTM F136 or polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) as described by ASTM F2026. Integral marker pins in the PEEK implants are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Substantial Equivalence: Documentation was provided which demonstrated the RABEA to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SIGNUS Medizintechnik GmbH
% Dr. Karen E. Warden, Ph.D.
Representative/Consultant
8202 Sherman Road
Chesterland, OH 44026-2141

JUL 24 2009

Re: K082848
Trade/Device Name: NUBIC™ and RABEA™ Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: July 22, 2009
Received: July 23, 2009

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:_____

Device Name: **NUBIC device**

Indications for Use:

When used as a vertebral body replacement, the NUBIC devices are indicated for use in skeletally mature patients to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The NUBIC device may be implanted singularly or in pairs and may be used with allograft or autograft.

When used as an intervertebral fusion device, the NUBIC devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One NUBIC device is used per intervertebral space. A connecting screw is available which allows the NUBIC device (without strut) to be physically attached to the SIGNUS TOSCA or TOSCA II anterior cervical plate systems if desired.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MXM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082848

Indications for Use Statement

510(k) Number:_____

Device Name: **RABEA device**

Indications for Use:

When used as a vertebral body replacement, the RABEA devices are indicated for use in skeletally mature patients to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The RABEA device is intended to be implanted in pairs and may be used with allograft or autograft.

When used as an intervertebral fusion device, the RABEA devices are intended for use in skeletally mature patients at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The devices are designed for use with autograft to facilitate fusion and intended for use with supplemental internal fixation. One RABEA device is used per intervertebral space.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MKM)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082848